K100720/52

EXHIBIT 4

NOV 1 9 2010

510(K) SUMMARY
June 21, 2010

1. SUBMITTER

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U.S. AGENT:

KAWASUMI LABORATORIES AMERICA, INC
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CONTACT: Mr. Jack Pavlo

2. NAME OF DEVICE: Kawasumi Laboratories Port Access Infusion Set with High Pressure Tubing
COMMON NAME: Port Access Infusion Set or Huber Needle Infusion Set
PROPRIETARY NAME: K-Shield Port Access Infusion Set with High Pressure Tubing
CLASSIFICATION: Class II, Codified at 21 CFR 880.5540.
PRODUCT CODE NUMBER: FPA

3. PREDICATE DEVICE: Kawasumi Laboratories Port Access Infusion Set with Antineedle Stick Protector (K060580), and, Bard Power Loc Safety Infusion Set (K060812)

4. DESCRIPTION OF THE DEVICE: The K-Shield Port Access Infusion Set with High Pressure Tubing is a sterile, single use device with a non-coring Huber needle (90 degree), non-DEHP polyvinyl chloride tubing with or without Y connector which incorporates an integral antineedle stick protector used to prevent accidental needlestick injuries. The set can withstand injection pressures to 300 psi for use with power injectors to inject contrast media into implanted ports designed for use with power injectors.

BASIC CONCEPT: The device is used for accessing an implanted medication port by puncturing the septum of the medication port and is used for the delivery of medication, blood sampling, and injection of solutions to 300 psi. Fluid administration through the non-DEHP polyvinyl chloride fluid pathway of the port access infusion set are those generally used in hospitals and for delivery of chemotherapy and contrast media. The device includes an integral antineedle stick device that when used prevent clinician's needle stick injuries

SIGNIFICANT PERFORMANCE CHARACTERISTICS: There are no new performance characteristics of this device compared to the substantially equivalent devices marketed for sale in interstate commerce. Both deliver fluids to the vascular system through a non reactive material and provide an integral antineedle stick protector feature.

5. INDICATIONS FOR USE: The K-Shield Port Access Infusion Set with High Pressure Tubing is an intravascular administration set with a non-coring Huber needle that is used to access an implanted medication port for solution infusion and blood sampling. The high pressure tubing allows for the injection of contrast media with a power injector to 300 psi into an implanted port indicated for use with a power injector. The device is supplied sterile, non-pyrogenic and for single use. The port access infusion sets are designed with an integral antineedle stick protector that provides a safety feature intended to minimize accidental needle stick injuries when the needle is activated during removal from the patient's implanted medication port.

6. TECHNOLOGICAL CHARACTERISTICS: The design and technological characteristics of the K-Shield Port Access Infusion Set with High Pressure Tubing are substantially equivalent to the identified predicate devices. The design technological characteristics of the K-Shield Port Access Infusion Set are identical to K060580 with the exception of the

following: 1) tubing can withstand injection pressure to 300 psi, 2) the tubing is composed of less plasticizer making the tubing suitable for high pressure power injections to 300 psi, 3) the product uses an open-ended Y connector with cap replacing the needleless Y connector, and 4) the female luer connector is composed of a different material. The technological characteristics of being able to withstand high pressure is substantially equivalent to the Bard device (K060812). The other identified differences do not have a significant impact on the safety or effectiveness of the device nor do they adversely affect the performance characteristics or biocompatibility of the device.

7. SUMMARY OF NON-CLINICAL TESTING DATA: The following testing was performed to determine the safety and effective of the high pressure tubing during use and assess the product's substantial equivalence to the listed predicate devices:

Test	Result
ISO 8536-4	Pass
ASTM D2240 -05	Pass
ISO 594-2: 1998	Pass
ISO 8536-4 : additional Pressure Testing	Pass
ISO 8536-4: tubing elongation testing	Pass
ISO 8536-4: Maximum tubing pressure	Pass
ISTA (International Safe Transit Association) 2A Transportation Test 2008	Pass
Kawasumi internal test to validate flow rate	Pass
Kawasumi internal test to validate pinch clamp pressure	Pass
ASTM F 1929 -98	Pass
EN-868-5	Pass
ASTM F 1608-00	Pass

8. PERFORMANCE DATA: Kawasumi Laboratories believe that the results of these tests show the device is suitable for its intended use.

9. CONCLUSIONS: The K-Shield Port Access Infusion Set with High Pressure Tubing is substantially equivalent to the identified predicate devices and performs as well as the predicate devices for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Kawasumi Laboratories, Incorporated
C/O Ms. Suzan Onel
K & L Gates LLP
1601 K Street N.W.
Washington, District of Columbia 20006

NOV 19 2010

Re: K100720
Trade/Device Name: K-Shiels Port Access Infusion Set with High Pressure Tubing
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: November 10, 2010
Received: November 12, 2010

Dear Ms. Onel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K100720

Device Name: K-Shield Port Access Infusion Set with High Pressure Tubing

Indications for Use:

The K-Shield Port Access Infusion Set with High Pressure Tubing is an intravascular administration set with a non-coring Huber needle that is used to access an implanted medication port for solution infusion and blood sampling. The high pressure tubing allows for the injection of contrast media with a power injector to 300 psi into an implanted port indicated for use with a power injector. The device is supplied sterile, non-pyrogenic and for single use. The port access infusion sets are designed with an integral antineedle stick protector that provides a safety feature intended to minimize accidental needle stick injuries when the needle is activated during removal from the patient's implanted medication port.

Prescription Use ✓ (Part 21 CFR §801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR §801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) 11/17/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K100720